NOV 0 9 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K012326 **"**

Introduction	According to the requirements of 21 CFR 862.1495, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.
1) Submitter name, address, contact	Wiener Lab Group Riobamba 2944 2000 – Rosario - Argentina Contact person: Viviana Cétola Date Prepared: March 20, 2001
2) Device name	Proprietary name: Mg-Color AA Common name: Magnesium test system Classification name: Photometric method, Magnesium as per 21 CFR Section 862.1495 Device Class I

3) Predicate Device

We claim substantial equivalence to the currently marketed ROCHE MAGNESIUM test system (Cat. Nº 1489330).

4) Device descriptions

Magnesium, in the presence of EGTA, is coupled with xylidyl blue in an alkaline solution.

Mg + Xylidyl blue ⟶ purple complex

EGTA in the reagent complexes with calcium, so that only magnesium react with the indicator. The intensity of purple complex color formed is proportional to the magnesium concentration and can be measured photometrically.

5) Intended use

The Mg-COLOR AA reagent is intended to be used in the quantitative determination of magnesium in human serum, plasma and urine. Magnesium measurement are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

6) Equivalencies and differences

The Wiener lab. Magnesium test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed ROCHE MAGNESIUM test system.

The following table illustrates the similarities and differences between the Wiener lab. Magnesium test system and the currently market ROCHE MAGNESIUM test system.

	ROCHE Test System	WIENER LAB. Test System
Intended use	Quantitative determination of magnesium in human serum, plasma and urine.	
Test principle	Magnesium, in the presence of EGTA, is coupled with xylidyl blue in an alkaline solution. Mg + Xylidyl blue ⟶ purple complex EGTA in the reagent complexes with calcium, so that only magnesium react with the indicator. The intensity of purple complex color formed is proportional to the magnesium concentration and can be measured photometrically.	
Essential Components	Xylidyl blue - EGTA	
Reagents	R1: Buffer/EGTA R2: Xylidyl Blue	R: Buffer/EGTA/ Xylidyl Blue
Reagent handling	Ready to use	
Instability or deterioration of reagents	Not specified	Reagent decoloration or decreased pH
Sample	Serum, heparinized plasma and urine	
Working Temperature Range	25 – 37ºC	
Stability of final color	Not specified	60 minutes
Wavelength range of reading.	505-600 nm	510 -600 nm

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	ROCHE Test System	WIENER LAB. Test System
Calibration	Single point	
Linearity	4.86 mg/dl	6.00 mg/dl
Minimum detection limit	0.07 mg/dl	0.08 mg/dl
Expected values	Serum and plasma: 1.58-2.55 mg/dl Urine: 60-210mg/24 hs 4.10-13.80 mg/dl	Serum and plasma: 1.9-2.5 mg/dl Urine: 50-150 mg/24 hs 1-10 mg/dl
Intra-assay precision	Normal Serum Control: CV = 0.8% Abnormal Serum Control: CV = 0.7% Human Urine 1 CV = 3.2% Human Urine 2 CV = 0.6%	Normal Serum Control: CV = 2.0% Abnormal Serum Control: CV = 1.9% Human Urine 1 CV = 1.5% Human Urine 2 CV = 1.5%
Inter-assay precision	Normal Serum Control: CV = 1.6% Abnormal Serum Control: CV = 2.6% Human Urine 1 CV = 6.3% Human Urine 2 CV = 1.6%	Normal Serum Control: CV = 2.6% Abnormal Serum Control: CV = 3.3% Human Urine 1 CV = 3.1% Human Urine 2 CV = 1.9%

7) Conclusion Based on the data above mentioned, we believe that the extended claims continue to support substantial equivalence to other products in commercial distribution intended for similar use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Viviana Cetola
QC/QA Manager
Wiener Laboratorios S. A. I.C.
Riobamba 2944,
Rosario, Santa Fe
Argentina

NOV 0 9 2001

Re: k012326
Trade/Device Name: Mg-color AA
Regulation Number: 21 CFR 862.1495
Regulation Name: Magnesium test system
Regulatory Class: Class I, reserved
Product Code: JGJ
Dated: October 1, 2001
Received: October 9, 2001

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012326

NOV 0 9 2001

510(k) Number (if known): K012326

Device Name: Wiener lab.
Mg-color AA

Indications For Use:

The "Wiener lab. Mg-color AA" test system is a device intended to be used in the quantitative determination of magnesium in human serum, plasma and urine. Magnesium measurement is used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

Ruth Chesler For Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012326

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

SK-U